



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,302	07/03/2003	Gary H. Posner	2938-116	3192

6449 7590 10/25/2005

ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER

BADIO, BARBARA P

ART UNIT PAPER NUMBER

1617

DATE MAILED: 10/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/612,302

Applicant(s)

POSNER ET AL.

Examiner

Barbara P. Badio, Ph.D.

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) 11,21,22 and 24-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10,12-20 and 23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 July 2005 and 04 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/2004</u> . | 6) <input type="checkbox"/> Other: ____. |

First Office Action on the Merits

Election/Restrictions

1. Applicant's election with traverse of Group I in the reply filed on September 6, 2005 is acknowledged. The traversal is on the ground(s) that the examiner has not established that searching of different methods of use would be an undue burden on the Office. This is not found persuasive because as indicated in the previous Office Action, claims 24-67 are directed to several different methods of using the claimed compounds and according to MPEP § 806.05(h), restriction is proper if the product as claimed can be used in materially different process of using. In addition, a search of the different uses would require different search strategies and a reference against one method of use might not be applicable to the other claimed uses. Thus, a search of the claimed methods of use would be an undue burden on the examiner.

The requirement is still deemed proper and is therefore made **FINAL**.

2. Based on applicant's election of Group I and the compound of formula I(a), claims 24-67 stand withdrawn from further consideration as being drawn to a nonelected invention. Claims 1-23 will be examined according to MPEP § 803.02. Therefore, claims 11, 21 and 22 stand withdrawn from further consideration as being drawn to a nonelected species.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 recites the limitation "selected from the group consisting of I(a), I(e)..." in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Claim 20 recites similar compounds and, thus, is rejected for the same reason.

Note: Parent claim 1 does not recite said compounds of formulae I(a), I(e)...as recited by claims 19 and 20. For the purpose of art rejection, it is assumed the claims are dependent on claim 18 that recites similar formulae.

5. Claims 10 and 18 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

The instant claim recites compounds wherein R⁴ is 4-nitrophenyl. However, "4-nitrophenyl" is not encompassed by the R⁴ group defined by parent claim 1.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4, 12-14, 17 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Posner et al. (J. Med. Chem., 1999).

Posner et al. teach sulfone analogues of 1 α ,25-dihydroxyvitamin D₃, such as compound 3a, and its antiproliferative property (see the entire article, especially page 3425, Results and Discussion; page 3426, Scheme 1, compound 3a). The compound and composition taught by the reference are encompassed by the instant claims.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-10, 12-20 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeLuca et al. (US 4,927,815).

DeLuca et al. teach vitamin D₃ derivatives having a phenylsulfone side chain (see the entire article, especially col. 4, lines 45-63). The reference teaches the compounds are useful in the preparation of vitamin D derivatives having biological properties (see for example, Process Scheme IV).

The instant claims differ from the cited reference by reciting compounds not exemplified by the reference. However, it would have been obvious to one having ordinary skill in the art at the time of the present invention to select any of the species of the genus taught by the reference, including that of the instant claims, because he would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, would be useful in the preparation of biologically active vitamin D derivatives as taught by the reference.

Other Matters

10. Claim 5, please amend to include a space between "to" and "claim 1".

Telephone Inquiry

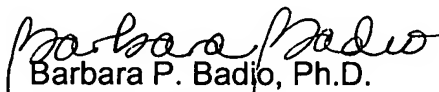
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax

Art Unit: 1617

phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1617

BB
October 24, 2005